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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,010

01/11/2006

Richard Anthony Borman

BJS-620-410

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EXAMINER

RAO, SAVITHA M

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,010	Applicant(s) BORMAN ET AL.	
	Examiner SAVITHA RAO	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92-111 is/are pending in the application.
- 4a) Of the above claim(s) 92-95 and 99-111 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 96-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/11/2006, 05/10/2006 and 06/05/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 92-111 are pending and are subject of this office action.

Claims 92-95 and 99-111 are withdrawn as being drawn to a non-elected invention and species.

Claims 96-98 are considered for examination in the current office action

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 01/11/2006, 05/10/2006 and 06/05/2006. The Examiner has considered the reference cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Election/Restrictions

Applicant's election with traverse of Group II (claims 96-98) in the reply filed on 10/03/2008 is acknowledged. The traversal is on the ground(s) that the Examiner did not demonstrate a lack of unity of invention as between any of the indicated groups of subject matter by citation of a novelty destroying document.

Examiner does not find the Applicant's argument persuasive. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of

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the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

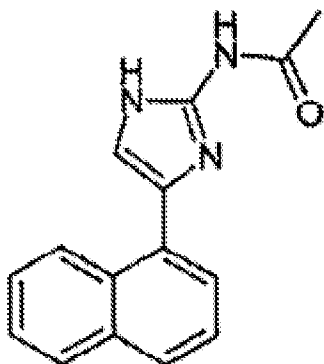
Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

In the instant application, the special technical feature of each of the Groups I through VIII are different (as detailed in page 6-7 of the restriction requirement dated

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09/03/2008.) Accordingly there is no same or corresponding special technical feature unifying Groups I through VIII and thereby they lack unity. Additionally, the instant application contain claims to more than one of the combinations of categories of inventions set forth above and accordingly unity of invention is not present.

Applicant's election with traverse of the following specie (103N from page 97 of the instant disclosure) for examination purposes is acknowledged



The traversal is on the grounds that that a search of all compounds of the elected subject matter is not believed to present an undue burden for the examiner and the Examiner has not demonstrated that the species of the elected group lack unity of invention.

Examiner does not find the Applicant's argument persuasive. The species encompassed by the elected subject matter are structurally divergent, differ in their physical, chemical and biological properties and activities and thereby require searching in different class/subclasses and use of different search queries. The reply must also identify the claims readable on the elected species, including any claims subsequently added.

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Furthermore, it is noted that Applicants' elected product claims are not in condition for allowance, thus, rejoinder at this time is not proper.

Claims 92-95 and 99-111 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/03/2008

Claims 96-98 are considered for examination in the current office action

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

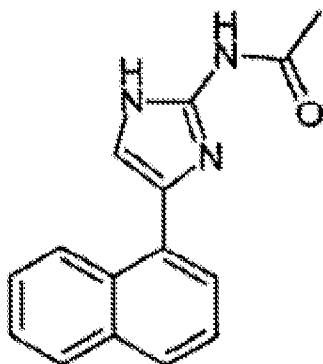
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 95-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doweyko (US 2006/0223110) as evidenced by Patani et al (Chemical Reviews, Vol 96 (8) 1996)

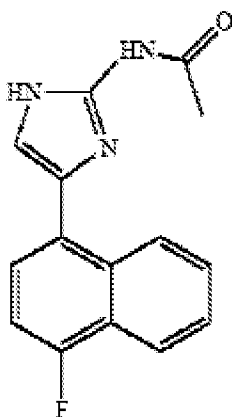
Instant claims are drawn towards the following compound (103N from page 97 of the instant disclosure)



Doweyko teaches the following compound (see below) as an intermediate in the

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reaction to generate the 4 (1-(4-fluoro)naphthyl)aminoimidazole (page 29, section [0317-0318]).



The only difference between the instantly claimed compound 103n and the compound taught by Doweyko is the substitution in the naphthyl ring with fluorine. However, Patani et al is used here for evidence that the F group and H group are bioisosters and one can be substituted by the other without any loss or change in activity. Patani teaches Fluorine and Hydroxyl, amino or methyl groups as replacements for hydrogen (Grimm's hydride displacement law) and teaches that the existence of this larger group of isosteres might be attributable to a greater tolerance of the different physicochemical parameters of these functionalities within a particular series of agents (page 3152, left col. 3rd paragraph). Patani additionally teaches an evaluation study of compounds as dual NEP (epithelial neutral endopeptidase) and ACE (angiotensin converting enzyme) where substitution of H with isosteres (-F, -OH, -NH₂) as described by Grimm's hydride displacement law resulted in retention of activity and no significant alteration in preferential activity with either of the peptidases, ACE or NEP, were observed for their bioisosteres (page 3152, left col. 5th paragraph to right col.

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1st paragraph).

Accordingly, it would have been *prima facie* obvious to the ordinarily skilled medicinal chemist to synthesize the instantly claimed compounds. Instantly claimed compound with fluorine substitution on the naphthyl ring instead of H is already taught in the art. In view of the close structural similarity between the instantly claimed compound and the compound taught by Doweyko one of ordinary skilled in the art would have been motivated to formulate instantly claimed compounds, substituting the fluorine group in Doweyko's compounds with other substituents such as H. One of the most common substitutions in a structural activity relationship studies in medicinal chemistry is the interchanging of hydrogen to a halogen substitution and vice versa. Accordingly, an ordinarily skilled medicinal chemist will be motivated to synthesize compounds taught by Doweyko without the fluoro substitution. A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and/or similar utilities. "An obviousness rejection based on similarity in chemical structure and/or function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).

Conclusion

Claims 96-98 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614